

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
 (Not for submission under 37 CFR 1.99)

Application Number	10517686
Filing Date	2004-12-10
First Named Inventor	Evert Johannes Bunschoten et al.
Art Unit	1616
Examiner Name	Mei-Ping Chui
Attorney Docket Number	0470-045923

U.S. PATENTS						<input type="button" value="Remove"/>
Examiner Initial*	Cite No	Patent Number	Kind Code†	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
1	6500814			2002-12-31	Hesch	
2	6214815			2001-04-10	Shangold et al.	
3	5827843			1998-10-27	Koninckx	
4	5662927			1997-09-02	Ehrlich et al.	
5	5633242			1997-05-27	Oettel et al.	
6	5468736			1995-11-21	Hodgen	
7	5340586			1994-08-23	Pike et al.	
8	5340585			1994-08-23	Pike et al.	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10517686
Filing Date	2004-12-10
First Named Inventor	Evert Johannes Bunschoten et al.
Art Unit	1616
Examiner Name	Mei-Ping Chui
Attorney Docket Number	0470-045923

9	5223261	1993-06-29	Nelson et al.	
10	5211952	1993-05-18	Spicer et al.	
11	5130137	1992-07-14	Crowley, Jr.	
12	5063507	1991-11-05	Lindsey et al.	
13	4937238	1990-06-26	Lemon	
14	4762717	1988-08-09	Crowley, Jr.	
15	4722941	1988-02-02	Eckert et al.	
16	4624665	1986-11-25	Nuwayser	
17	4573996	1986-03-04	Kwiatek et al.	
18	4460372	1984-07-17	Campbell et al.	
19	3797494	1974-03-19	Zaffaroni	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10517686
Filing Date	2004-12-10
First Named Inventor	Evert Johannes Bunschoten et al.
Art Unit	1616
Examiner Name	Mei-Ping Chui
Attorney Docket Number	0470-045923

	20	3440320		1969-04-22	Sackler et al.	
--	----	---------	--	------------	----------------	--

If you wish to add additional U.S. Patent citation information please click the Add button.

**U.S.PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No	Publication Number	Kind Code <sup>1</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button

**FOREIGN PATENT DOCUMENTS**

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> i	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	1700602	EP	A1	2001-05-18	Pantarhei Bioscience B.V		<input type="checkbox"/>
	2	0130357	WO	A	2001-05-03	Theramex		<input type="checkbox"/>
	3	0062753	WO		2000-10-26	Jenapharm GmbH & Co.		<input type="checkbox"/>
	4	9858657	WO	A1	1998-12-30	Mannaerts et al		<input type="checkbox"/>
	5	9502408	WO	A1	1995-01-26	Schering		<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10517686
Filing Date	2004-12-10
First Named Inventor	Evert Johannes Bunschoten et al.
Art Unit	1616
Examiner Name	Mei-Ping Chui
Attorney Docket Number	0470-045923

6	9426207	WO		1994-11-24	University of Southern California		<input type="checkbox"/>
7	9218107	WO	A1	1992-10-29	University of Southern California		<input type="checkbox"/>
8	468690	EP	A1	1991-07-17	Sumitomo Chemical Co., Ltd.		<input type="checkbox"/>
9	0402950	EP	A	1975-12-18	Oron Yhtymae OY		<input type="checkbox"/>
10	2426779	DE	A1	1975-12-18	Schering AG		<input type="checkbox"/>
11	2336434	DE	A1	1975-04-17	Schering AG		<input type="checkbox"/>
12	2336433	DE	A1	1975-04-03	Schering AG		<input type="checkbox"/>
13	9603929	WO	A1	1966-02-15	Biox, Inc.		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

Add

**NON-PATENT LITERATURE DOCUMENTS**

Remove

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T6
	1	VISSEER et al., "In vitro effects of estrelol on receptor binding, drug targets and human liver cell metabolism," CLIMACTERIC (2008) 11(1) Appx. II: 1-5.	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10517686
Filing Date	2004-12-10
First Named Inventor	Evert Johannes Bunschoten et al.
Art Unit	1616
Examiner Name	Mei-Ping Chui
Attorney Docket Number	0470-045923

2	VISSEER et al., "First human exposure to exogenous single-dose oral estetrol in early postmenopausal women," CLIMACTERIC (2008) 11(1): 1-10.	<input type="checkbox"/>
3	VISSEER et al., "Clinical applications of estetrol," J. Of Steroid Biochem and Molecular Biol. (2009) 114: 85-89.	<input type="checkbox"/>
4	HOLINKA et al., "Estetrol: A unique steroid in human pregnancy," J. of Steroid Biochem and Molecular Biol. (2009) 110: 138-143.	<input type="checkbox"/>
5	COELINGH BENNINK et al., "Oral bioavailability and bone sparing effects of estetrol in an osteoporosis model," CLIMACTERIC (2008) 11 (Supp 3): 1-13.	<input type="checkbox"/>
6	ALBERTAZZI PAOLA et al., "The Effect of Tibolone Versus Continuous Combined Norethisterone Acetate and Oestradiol on Memory, Libido and Mood of Postmenopausal Women: A Pilot study"; Database Biosis 'Online'; 10/31/2000; pages 223-229; Vol. 36, No. 3; Biosciences Information Service, Philadelphia, PA., U.S.	<input type="checkbox"/>
7	MUECK et al., "Angio and Anti-Angiogenetic Effects of Estradiol and its Metabolites", J. Clin. Basic Cardiol., 2001, pp. 153-155, Vol. 4, No. 2.	<input type="checkbox"/>
8	SHAH et al., "Estrogen and Skin. An Overview", Am. J. Clin. Dermatol., 2001, pp. 143-150, Vol. 2, No. 3.	<input type="checkbox"/>
9	SITRUK-WARE et al., "Local Hormonal Treatment for Urogenital Atrophy After Menopause", Schweiz. Rundsch. Med. Praxis, 1997, pp. 1245-1248, Vol. 86, No. 33, and SITRUK-WARE, English Translation, 1997. Praxis, Schwerzerische Rundschau fur Medizin, Vol. 86, No. 33, pp 1-13.	<input type="checkbox"/>
10	SCHMIDT et al., "Treatment of Skin Aging with Topical Estrogens", Int. J. Dermatol., 1996, pp. 669-674, Vol. 35, No. 9.	<input type="checkbox"/>
11	YOUNGLAI ET AL., Journal of Clinical Endocrinology and Metabolism, 1968, Vol. 28, Issue 11, pp 1611-1617.	<input type="checkbox"/>
12	Webster Ninth New Collegiate Dictionary, 2000, Definition of Prevention, pg 1.	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10517686
Filing Date	2004-12-10
First Named Inventor	Evert Johannes Bunschoten et al.
Art Unit	1616
Examiner Name	Mei-Ping Chui
Attorney Docket Number	0470-045923

13	WILLHITE ET AL., <i>Pharmacotherapy</i> , 2001, Vol. 21, Issue 4, pp 464-480.	<input type="checkbox"/>
14	SEEGER et al., "The inhibitory effect of endogenous estrogen metabolites on copper-mediated in vitro oxidation of LDL", <i>Int. Journal of Clinical Pharmacology and Therapeutics</i> , (1998), Vol. 36, No. 7, pp 383-385.	<input type="checkbox"/>
15	KUIPERS ET AL., "Enterohepatic Circulation in the Rat", <i>Gastroenterol.</i> , Vol. 88, pp 403-411 (1985).	<input type="checkbox"/>
16	SCHWARTZ, "A Model for the Regulation of Ovulation in the Rat", <i>Recent Prog. Horm. Res.</i> , Vol. 25, pp 1-55, (1969).	<input type="checkbox"/>
17	BEATTIE ET AL., "The Differential Effects of Diestrous Progestogen Administration on Proestrous Gonadotrophin Levels", <i>Endocrinol.</i> , Vol 97, pp. 885-890, (1975).	<input type="checkbox"/>
18	DE VISSER ET AL., "Endocrinological Studies with (7a, 17 a)-17-Hydroxy-7-me norpregn-5(10)-en-20-yn-3-one (Org OD 14), <i>Arzneim. Forsh.</i> , Vol. 34, pp 1010-1020, (1984).	<input type="checkbox"/>
19	National Cancer Institute: Breast cancer prevention retrieved online 08/07/2007 from the internet; <a href="http://www.cancer.gov/templates/doc.aspx?viewed=D972A74B-D25A-4F86-B8ED-33EB3C0450E4&amp;version">http://www.cancer.gov/templates/doc.aspx?viewed=D972A74B-D25A-4F86-B8ED-33EB3C0450E4&amp;version</a> , page 1.	<input type="checkbox"/>
20	Medline Plus. Medical Encyclopedia: Ovarian cancer retrieved online on 08/09/2007 from the internet: <a href="https://www.nlm.nih.gov/medlineplus/ovariancancer.html">https://www.nlm.nih.gov/medlineplus/ovariancancer.html</a> , page 1 dated 07/31/2007.	<input type="checkbox"/>
21	National Institute of Child Health and Human Development, NIH Publication No. 02-2413 retrieved online on 08/09/2007.	<input type="checkbox"/>
22	Breast Cancer Prevention retrieved online 08/07/2007 from the internet; <a href="http://www.cancer.gov/cancertopics/pdq/prevention/breast/Patient/page_3">http://www.cancer.gov/cancertopics/pdq/prevention/breast/Patient/page_3</a> .	<input type="checkbox"/>
23	ZIPS ET AL., <i>in vivo</i> , 2005, Vol. 19, pp. 1-8.	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10517686
Filing Date	2004-12-10
First Named Inventor	Evert Johannes Bunschoten et al.
Art Unit	1616
Examiner Name	Mei-Ping Chui
Attorney Docket Number	0470-045923

24	HOLINKA ET AL., <i>Biology of Reproduction</i> , 1980, Vol. 22, pp. 913-926.	<input type="checkbox"/>
25	MARTUCCI et al., "Impact of Continuously Administered Catechol Estrogens on Uterine Growth and Luteinizing Hormone Secretion", <i>Endocrinology</i> (Dec. 1979), Vol. 105, No. 6, pp. 1288-1292.	<input type="checkbox"/>
26	WEIGERT et al., "Comparison of Stimulation with Clomiphene Citrate in Combination with Recombinant Follicle Stimulating Hormone and Recombinant Luteinizing Hormone to Stimulation with a Gonadotropin-Releasing Hormone Agonist Protocol: A Prospective Randomized Study", <i>Fertility and Sterility</i> , (July 2002), Vol 78, No. 1, pp. 34-39.	<input type="checkbox"/>
27	TROTTER et al., "Effects of Postnatal Estradiol and Progesterone Replacement in Extremely Preterm Infants", <i>J. Clin. Endocrinol Metab.</i> , (Dec 1999), Vol. 84, No. 12, pp. 4531-5.	<input type="checkbox"/>
28	SHANKLIN et al., "Aqueous Estrogens in the Management of Respiratory Distress SYndrome", <i>J. Reprod. Med.</i> (Aug. 1970), Vol. 5, No. 2, pp. 53-71.	<input type="checkbox"/>
29	CHEMICAL ABSTRACTS SERVICE, Columbus Ohio, US: JAKOWICKI, "Evaluation of Estriol Level in the Amniotic Fluid in Prolonged Pregnancy", XP002458625.	<input type="checkbox"/>
30	GORWILL et al., "Unconjugated Serum Oestriol Levels in Mother and Baby with Meconium Staining of the Amniotic Fluid", <i>Br. J. Obstet. Gynaecol.</i> (Aug. 1978), Vol. 85, No. 8, pp. 602-4.	<input type="checkbox"/>
31	FOGARY, JR., "Postmaturity", <i>J. Am. Osteopath. Assoc.</i> , (Jan. 1976), Vol. 75, No. 5, pp. 512-7.	<input type="checkbox"/>
32	Office Action mailed on January 11, 2008 in U.S. Patent Application No. 10/478,262.	<input type="checkbox"/>
33	Office Action mailed on May 15, 2008 in U.S. Patent Application No. 10/478,262.	<input type="checkbox"/>
34	Office Action mailed on February 19, 2009 in U.S. Patent Application No. 10/478,262.	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10517686
Filing Date	2004-12-10
First Named Inventor	Evert Johannes Bunschoten et al.
Art Unit	1616
Examiner Name	Mei-Ping Chui
Attorney Docket Number	0470-045923

35	Office Action mailed on June 9, 2009 in U.S. Patent Application No. 10/478,262.	<input type="checkbox"/>
36	Office Action mailed on November 18, 2008 in U.S. Patent Application No. 10/478,264.	<input type="checkbox"/>
37	Office Action mailed on May 22, 2009 in U.S. Patent Application No. 10/478,264.	<input type="checkbox"/>
38	Office Action mailed on March 17, 2008 in U.S. Patent Application No. 10/478,357.	<input type="checkbox"/>
39	Office Action mailed on May 16, 2008 in U.S. Patent Application No. 10/478,357.	<input type="checkbox"/>
40	Office Action mailed on December 16, 2008 in U.S. Patent Application No. 10/478,357.	<input type="checkbox"/>
41	Office Action mailed on May 28, 2009 in U.S. Patent Application No. 10/478,357.	<input type="checkbox"/>
42	Office Action mailed on April 6, 2007 in U.S. Patent Application No. 10/478,365.	<input type="checkbox"/>
43	Office Action mailed on September 7, 2007 in U.S. Patent Application No. 10/478,365.	<input type="checkbox"/>
44	Office Action mailed on April 1, 2008 in U.S. Patent Application No. 10/478,365.	<input type="checkbox"/>
45	Office Action mailed on June 8, 2009 in U.S. Patent Application No. 10/478,365.	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number	10517686
Filing Date	2004-12-10
First Named Inventor	Evert Johannes Bunschoten et al.
Art Unit	1616
Examiner Name	Mei-Ping Chui
Attorney Docket Number	0470-045923

46	Office Action mailed on January 24, 2007 in U.S. Patent Application No. 10/495,707.	<input type="checkbox"/>
47	Office Action mailed on December 28, 2007 in U.S. Patent Application No. 10/495,707.	<input type="checkbox"/>
48	Office Action mailed on August 19, 2008 in U.S. Patent Application No. 10/495,707.	<input type="checkbox"/>
49	Office Action mailed on May 22, 2009 in U.S. Patent Application No. 10/495,707.	<input type="checkbox"/>
50	Office Action mailed on October 15, 2007 in U.S. Patent Application No. 10/517,509.	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature	Date Considered
--------------------	-----------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.